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TITLE: Is Homeopathy Effective for Hot Flashes and Other
Estrogen-Withdrawal Symptoms in Breast Cancer Survivors?
A Preliminary Randomized Controlled Trial

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13. ABSTRACT (Maximum 200 Words) <p><u>Background</u>- Hot flashes, and other symptoms of estrogen withdrawal, are common in breast cancer survivors. The standard treatment for these symptoms, hormone replacement therapy, is contraindicated in breast cancer survivors. Homeopathic medicines have been used to treat hot flashes and other menopausal symptoms for more than 100 years.</p> <p><u>Objectives</u>- To carry out a pilot study to determine whether there is evidence that homeopathy is an effective treatment to improve the quality of life in breast cancer survivors who are experiencing hot flashes and other menopausal-type symptoms.</p> <p><u>Methods</u>- A randomized double-blind placebo controlled trial will be carried out in a group of 105 breast cancer survivors with hot flashes and other menopausal symptoms. Subjects will be recruited from the Comprehensive Breast Center at Providence Hospital in Seattle and other affiliated clinics. Subjects should have a history of hot flashes for at least one month, with an average of at least 3 hot flashes per day. Subjects will be randomized to one of three treatment arms: classical homeopathy, a combination homeopathic remedy, or placebo. Number of hot flashes, menopausal index scores, general health status, patient satisfaction, and the use of health care services will be measured over a period of 12 months.</p>					
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Table of Contents

Cover.....	1
SF 298.....	2
Table of Contents.....	3
Introduction.....	4
Body.....	4
Key Research Accomplishments.....	5
Reportable Outcomes.....	5
Conclusions.....	6
References.....	6
Appendices.....	6

INTRODUCTION

Hot flashes, and other symptoms of estrogen withdrawal, are common in both pre- and post-menopausal breast cancer survivors. The standard treatment for these symptoms, hormone replacement therapy, is contraindicated in breast cancer survivors due to fear that it will stimulate tumor growth. Homeopathic medicines have been used to treat hot flashes and other menopausal symptoms for more than 100 years. Our goal is to determine whether homeopathy is an effective treatment to improve the quality of life in breast cancer survivors who are experiencing hot flashes and other menopausal-type symptoms. We plan to do a pilot study that demonstrates our ability to successfully conduct a full-scale trial. A randomized double-blind placebo controlled trial will be carried out in a group of 105 breast cancer survivors with hot flashes and other menopausal symptoms. Subjects will be randomized to one of three treatment arms: classical homeopathy, a combination homeopathic remedy, or placebo. Number of hot flashes, menopausal index scores, general health status, patient satisfaction, and the use of health care services will be measured over a period of 12 months.

BODY

The following research accomplishments have been achieved in the first year of the study. No statistical tests have been carried out or findings presented as we are still in the data collection phase of the study and the randomization code has not been broken.

Task 1. Preparation for Enrollment of Patients

- a. Letters were sent to 14 physicians at Providence Comprehensive Breast Center and affiliated clinics explaining the study and asking for patient referrals.
- b. Letters were sent to 12 breast cancer support groups describing the study and asking for volunteers
- c. Letters were sent to 87 potential subjects describing the study and including a self-administered eligibility checklist.
- d. Telephone screening of 107 interested subjects was carried out and 55 potential subjects were scheduled for screening appointments.
- e. Patient questionnaires and telephone follow-up instruments to assess outcomes were prepared and training of the Research Assistant in telephone procedure was done.
- f. Data entry screens for patient intake and follow-up data collection were created and training of the Research Assistant for data entry was accomplished.

Task 2. Enrollment of Subjects

- a. Eligibility of prospective subjects was confirmed at screening appointments, informed consent was confirmed, and baseline questionnaire data was collected
- b. A total of 54 patients have been enrolled in the first 9 months of study recruitment. The recruitment period has been extended and approval has been obtained to recruit patients from Swedish Medical Center, which recently acquired Providence Medical Center, where the initial subjects were recruited.

- c. Initial homeopathic consultation and randomization of subjects to one of three treatment groups has been carried out on 49 subjects. Medicines have been mailed to all subjects according to the protocol schedule.
- d. Telephone interviews have been conducted at 1 (42 subjects), 2 (39 subjects), and 3 (30 subjects) months after randomization to assess progress and collect outcomes information. Hot flash diaries have been mailed and collected for the week prior to each of these calls.
- e. Follow-up homeopathic consultations have been conducted at 2 (37 subjects and 4 (28 subjects) months after the initial homeopathic visit.
- f. Data entry of initial consultations and follow-up visits has been done as they occur, as well as the information collected during telephone interviews.

Task 3. Patient Follow-up

- a. Telephone interviews at 6 (15 subjects) and 9 (1 subject) months after randomization to assess progress and collect outcomes information. Hot flash diaries have been mailed and collected for the week prior to each of these calls.
- b. Follow-up homeopathic consultations at 6 (12 subjects) and 8 (3 subjects) months after the initial homeopathic visit have been conducted.
- c. Data entry of follow-up visits has continued as they occur, as well as information collected during telephone interviews.
- d. Annual report for Year I has been prepared.

Our biggest challenge has been in patient recruitment, which has been slower than anticipated. We plan to address this by expanding recruitment to potential subjects from Swedish Medical Center, which recently acquired Providence Medical Center, the facility from which initial subjects were recruited. Swedish has a large breast cancer data registry containing 1500 names from which potential subjects will be identified.

Another area that has been problematic is in the use of three study arms: classical homeopathy, a combination homeopathic medicine, and placebo. Because of this design, we have used a "double-dummy" design, whereby all subjects are taking two types of medicines, one or both of which might be placebo. This has been confusing to many subjects as well as to the homeopathic prescribers, who have difficulty making treatment decisions because of the uncertainty as to which treatment group a patient might be assigned.

KEY RESEARCH ACCOMPLISHMENTS

None so far as we are still in the recruitment and data collection phase of this study

REPORTABLE OUTCOMES

None

CONCLUSIONS

Because the research is ongoing, it is too soon to make any conclusions at this time. We have found that study recruitment has been difficult and would recommend that additional strategies be used in future studies to facilitate this process. Also, the “double dummy” design has been difficult to execute and in future studies we would recommend that two treatment arms be used (active medication or placebo) for each of the 2 homeopathic treatment strategies.

REFERENCES/APPENDICES

None